

## MEDICAL INSTRUMENT

### TECHNICAL FIELD

[0001] The present invention relates to a medical instrument (a catheter device) that cuts deposits from a narrowed coronary artery or other vascular site with a rotating cutter means to establish patency of a passageway through the vascular site or to distend the narrowed vessel.

### BACKGROUND ART

[0002] To treat a disease caused by deposits on the wall of a blood vessel, it is customary to insert a catheter device into a patient's body down to an intravascular treatment site to remove the deposits or to distend the narrowed vessel.

[0003] Fig. 11 is a schematic diagram explanatory of a procedure for scraping deposits off the wall of a blood vessel.

[0004] The first thing to do is to insert a small-diameter guide wire 105 into a blood vessel 101 and navigate it past a narrowed vascular site 107, followed by inserting a small-diameter catheter device 125 into the vessel along the guide wire 105. The catheter device 125 has a shell-like grindstone 127 and a drive shaft 129 formed by a coiled wire. The next step is to drive the grindstone 127 of the catheter device 125 at high speed (approximately 200,000 rpm, for instance) to grind away deposits 103 to broaden first the entrance of the narrowed vascular site 107 up to a diameter of around 1 mm for ease in centering the grindstone 127, which is then inserted in its entirety through the narrowed vascular portion.

[0005] Following this, the catheter device 125 is pulled out of the vessel, with the guide wire 105 left remaining therein intact, and another catheter device with a slightly larger-diameter grindstone is inserted into the vessel along the guide wire and is driven to scrape the deposits 103 in the same manner as mentioned above. This operation is repeated using catheter devices that are replaced one after another in ascending order of grindstone diameter to gradually enlarge the diameter of the narrowed vascular portion 107 up to an ultimate value of approximately 2.5 mm.

[0006] In this way, the catheter device has a rotary cutting bar (the grindstone 127) held rotatable and slidable with respect to the guide wire 105 passing through the narrowed vascular site, and

drives the rotary cutting bar at high speed to thereby grind away calcified deposits on the wall of the narrowed blood vessel.

[0007] The above-mentioned conventional rotary cutting bar (a rotor ablator, the grindstone 127 in Fig. 11) has a rigid structure that has the bar surface formed by a grinding surface coated with abrasive grains, but has no vessel distending mechanism. On this account, in a case where it is desirable to distend a narrowed blood vessel to a diameter larger than that obtained by previous removal of calcified deposits, the rotary cutting bar (grindstone 127) needs to be completely pulled off from the guide wire (105), together with the drive shaft (129), and exchanged for a rotary cutting bar of a larger diameter. In nearly 40% of the past cases, two large- and small-diameter versions were used for each of the rotary cutting bar (grindstone 127) and the drive shaft (129) (an average number used per case being 1.4), and they needed complicated replacement work in a clean region in an operating room.

[0008] In this respect, since the conventional rotary cutting bar (a rotor ablator, a grindstone) is held unitary with the drive shaft, its replacement is required to follow the below-listed steps 1 to 7, and hence it is complicated.

[0009] The procedure for replacement comprises the steps of:

1. Disengaging the drive shaft (129 in Fig. 11) from a drive control assembly;
2. Pulling the drive control assembly off the guide wire;
3. Pulling the rotary cutting bar and the drive shaft (grindstone 127 and drive shaft 129) out of a patient's body in their entirety and then pulling them off the guide wire, too;
4. Putting a rotary cutting bar and a drive shaft (grindstone 127 and drive shaft 129), both larger in diameter, on the guide wire;
5. Navigating the rotary cutting bar (grindstone 127) to a treatment site in a coronary artery;
6. Putting the drive control assembly on the guide wire; and
7. Operatively connecting the drive control assembly to the larger-diameter rotary cutting bar and drive shaft (grindstone 127 and drive shaft 129).

[0010] Another problem is that abrasive grains may fall off the cutting surface of the rotary cutter. That is, the cutting surface of the rotary cutter is formed by coating the mother metal

surface with diamond abrasive grains by chromium plating (diamond electrodeposition), but there is a fear that, during cutting of deposits in the narrowed vascular portion, the diamond grains may fall off due to a cutting reaction force by hard calcified deposits and may flow downstream in the vessel, blocking peripheral blood vessels.

[0011] Still another problem is a strong possibility that when the diamond-electrodeposited grindstone of the conventional rotor ablator is deformed to expand, the electrodeposited diamond abrasive grain layer may come off in scales from the mother material.

[0012] In view of the above-mentioned problems, the present invention has for its object to provide a medical instrument that, in the case of distending a narrowed vascular portion after initial treatment, permits enlargement of the diameter of the rotating cutter on the guide wire left remaining in the blood vessel, without the need for pulling the rotating cutter off the guide wire.

[0013] Another object of the present invention is to provide a medical instrument that allows easy enlargement of the diameter of the rotating cutter on the guide wire after once pulling the rotating cutter out of a patient's body along the guide wire left remaining in the blood vessel.

[0014] Still another object of the present invention is to provide a medical instrument that permits quick and effective removal of an intravascular narrowing material by a rotating cutter.

#### DISCLOSURE OF THE INVENTION

[0015] To solve the above-described problem, the medical instrument of the present invention comprises:

    a guide wire that is inserted at one end through a vascular portion narrowed by deposits and is extended at the other end out of a patient's body;

    a rotating cutter that is rotatably and slidably guided over said guide wire and is driven to cut away the deposits in said narrowed vascular portion;

    a hollow drive shaft that is operatively connected to said rotating cutter and through which said guide wire is inserted;

    a fixed sheath having inserted therein said drive shaft; and

    a controller having a drive assembly for rotating said drive shaft;

    wherein said rotating cutter is driven to perform intravascular treatment to establish

patency of said narrowed vascular portion or to distend said vascular portion;

wherein:

a secondary treatment rotating cutter, whose cutting surface has an outside diameter larger than the maximum diameter of the cutting surface of said rotating cutter (the initial treatment rotating cutter), is disposed on that part of said guide wire extending out of the patient' body; and

in the case of further distending said narrowed vascular portion after cutting treatment of said narrowed vascular portion by said initial treatment rotating cutter, said initial treatment rotating cutter is once pulled out of the patient's body along said guide wire, together with said drive shaft and said fixed sheath, then said secondary treatment rotating cutter is coupled on said guide wire to said initial treatment rotating cutter to form a one-piece cutter assembly of enlarged outside diameter, and said cutter assembly (a unit cutter) is inserted again into the patient's body to perform further distending treatment of said narrowed vascular portion.

[0016] In the medical instrument of the present invention, the secondary treatment rotating cutter can be joined to the initial treatment rotating cutter by engage-and-lock or press-fit means.

[0017] In this instance, the medical instrument can be used to perform treatment for distending the narrowed vascular portion by cutting deposits therein without a fear of disengagement of the both cutter from each other.

[0018] In the medical instrument of the present invention, the curved cutting surface of the initial treatment rotating cutter can be covered with the secondary treatment rotating cutter through plastic deformation of the latter in conformity to the outer peripheral surface of the former.

[0019] In this case, the both cutters can be united with sufficient mechanical strength to prevent their disengagement.

[0020] In the medical instrument of the present invention, the secondary treatment rotating cutter can be disposed in advance coaxially with or in proximity to the drive shaft.

[0021] In the case of performing treatment for further distending the narrowed vascular portion after initial deposit removal treatment, the secondary treatment rotating cutter can be promptly united with the initial treatment rotating cutter once drawn out of the patient's body along the

guide wire. Accordingly, step-by-step treatment for removing deposits from the narrowed vascular portion can be performed promptly without undue interruption.

[0022] In the medical instrument of the present invention, the secondary treatment rotating cutter is set on the initial treatment rotating cutter by a jig disposed in advance coaxially with or in proximity to the drive shaft.

[0023] In this case, since the jig is always kept near the drive shaft, the both cutters can promptly be united efficiently.

[0024] In the medical instrument of the present invention, the jig can be equipped with a one-hand operated, squeeze-type lever mechanism that utilizes a force-multiplying mechanism by a lever or cam.

[0025] In this case, the initial treatment rotating cutter and the secondary treatment rotating cutter can easily be united.

[0026] In the medical instrument of the present invention, the initial treatment rotating cutter and the secondary treatment rotating cutter have their cutting surfaces formed by grooves or cutting edges made in their outer peripheral surfaces.

[0027] Since the conventional cutting bar is coated all over the mother metal surface of the rotating grindstone with diamond abrasive grains by chromium plating or electrodeposition, there are cases where the diamond grains may fall off due to a cutting reaction force by hard calcified deposits, inducing occlusion of peripheral blood vessels. In contrast to this, the rotating cutter of the present invention is free from the fear of such falling-off of grains since the cutting surface is formed by cutting edges.

[0028] In the medical instrument of the present invention, the afore-mentioned controller has a mechanism for pushing the initial treatment rotating cutter out forwardly from a distal end of the fixed sheath toward the patient side and a mechanism for retracting the initial treatment rotating cutter in a reverse direction, and these mechanisms can be adapted for actuation by a squeeze-type operating lever provided with an auto-return mechanism and a position retaining mechanism.

[0029] This allows ease in pushing out the rotating cutter forwardly from the distal end of the fixed sheath toward the patient side and in retracting the rotating cutter.

[0030] In the medical instrument of the present invention, the controller can be provided with a vibrating mechanism for reciprocating the initial treatment rotating cutter along said guide wire.

[0031] In this case, since combined cutting forces by rotary and reciprocating motions can be imparted to the rotating cutter, it is possible to increase or stabilize the cutting force of the rotating cutter for removing deposits from the narrowed vascular portion. Besides, the rotating cutter and the fixed sheath can easily be inserted into a guiding catheter with less friction.

[0032] In the medical instrument of the present invention, a drive assembly in the controller for rotating the drive shaft can be adapted to include a motor having a hollow rotary shaft which permits the insertion therethrough of the drive shaft.

[0033] This allows ease in pulling out the drive shaft from the patient's body along the guide wire without the need for completely removing the drive shaft from the guide wire.

[0034] In the medical instrument of the present invention, the controller can be adapted to include a drive shaft chucking mechanism and a soft sheath attaching/detaching mechanism.

[0035] In this case, the chucking mechanism ensures transmission of driving force to the drive shaft. Furthermore, in the case of, for example, maintenance for the inside of the controller, the fixed sheath can be easily taken away from the controller.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0036] Fig. 1 is a perspective view for explaining the usage pattern of a medical instrument according to a first embodiment of the present invention.

[0037] Fig. 2 is a perspective view showing, on an enlarged scale, a controller of the medical instrument of Fig. 1.

[0038] Fig. 3 is a partially sectioned and broken-away perspective view showing the controller of Fig. 2.

[0039] Fig. 4(A) is a partially sectioned side elevational view showing, in association with a jig, an initial treatment rotating cutter and a secondary treatment rotating cutter before they are joined together, and 4(B) is a partially sectioned side elevational view showing the both cutters of Fig. 4(A) after they are joined together.

[0040] Fig. 5 is a partially sectioned side elevational view of a rotating cutter diameter enlarging jig of a medical instrument according to a second embodiment of the present invention.

[0041] Figs. 6(A) through 6(D) are partially sectioned side elevational views showing, in association with a jig, a rotating cutter of a medical instrument according to a third embodiment of the present invention.

[0042] Fig. 7 is a perspective view showing an initial treatment rotating cutter and a secondary treatment rotating cutter of a medical instrument according to a fourth embodiment of the present invention.

[0043] Fig. 8 is a sectioned side elevational view showing the construction of a controller of a medical instrument according to a fifth embodiment of the present invention.

[0044] Fig. 9 is a sectioned side elevational view showing, on an enlarged scale, the construction of the principal part of the controller depicted in Fig. 8.

[0045] Fig. 10 is a sectioned side elevational view showing the controller of the Fig. 8 medical instrument, with a sheath connector taken away.

[0046] Fig. 11 is a schematic diagram for explaining how to scrape off deposits.

#### BEST MODE FOR CARRYING OUT THE INVENTION

[0047] To facilitate a better understanding of the present invention, the best mode for carrying out the invention will hereinafter be described with reference to the accompanying drawings.

#### [0048] EMBODIMENT 1

[0049] Fig. 1 is a perspective view explanatory of the usage pattern of the medical instrument according to a first embodiment of the present invention.

[0050] At the lower left of Fig. 1 there is shown a narrowed vascular portion 2 at a treatment site. In the illustrated state a distal end portion of the medical instrument is inserted through the narrowed vascular portion 2.

[0051] This medical instrument has a guide wire 1. The guide wire 1 is passed at a distal end through the narrowed vascular portion 2 while its proximal end portion is extended out of a patient's body. On the guide wire 1 there is held a rotating cutter (an initial treatment rotating cutter) 3. The initial treatment rotating cutter 3 rotates about the guide wire 1, and is slidably over the guide wire 1. Incidentally, the rotating cutter 3 will be described in detail later on.

[0052] The rotating cutter 3 is affixed at a proximal end to a drive shaft 4. The drive shaft 4 is a hollow member made of a soft and flexible material. The drive shaft 4 is slidably inserted through a fixed sheath 5 that is a flexible cover tube. The fixed sheath 5 is inserted through a guiding catheter 6. The guiding catheter 6 is connected at a proximal end to a controller 10. The controller 10 has built therein a drive mechanism for rotating and reciprocating the drive shaft 4 at high speed.

[0053] Turning next to Figs. 2 and 3, the controller 10 will be described in detail.

[0054] Fig. 2 is an enlarged perspective view illustrating the controller of the medical instrument depicted in Fig. 1.

[0055] Fig. 3 is a partially broken-away, sectioned perspective view of the controller shown in Fig. 2.

[0056] As shown in Figs. 2 and 3, the controller 10 is provided with a rotating cutter (a secondary treatment rotating cutter) 7. The rotating cutter 7 is one that is different from the afore-mentioned initial treatment rotating cutter 3. The secondary treatment rotating cutter 7 is rotatably and slidably held on that section of the drive shaft 4 which is extended out of a patient's body. The rotating cutter 7 is releasably seated in a base concavity 12 made in a front wall of a housing 11 of the controller 10.

[0057] To the front end of the housing 11 of the controller 10 there is slidably attached a jig 13. The jig 13 is one that interengages the initial treatment rotating cutter 3 and the secondary

treatment rotating cutter 7 into a one-piece structure. The jig 13 has at its front extremity a tab 13a bent upward. The tab 13a is bent upward from the marginal edge of the front end portion of the jig 13 (which extends forwardly of the front end face of the housing 11). The tab 13a has a slit 13b. On the other hand, the jig 13 has at its rear extremity a cam engaging piece 13c (see Fig. 3) bent upward from the marginal edge of the rear end portion of the jig (lying within the housing 11). Though not shown in Figs. 2 and 3, the tab 13a has made therein a cutter receiving concavity 13d in opposing relation to the base concavity 12 (see Figs. 4 and 5).

[0058] A jig operating lever 14 is pivotally secured to the housing 11 of the controller 10. To a rotary shaft of the operating lever 14 is coupled a cam 15. The cam 15 is in engagement with a cam engaging piece 13c forming the rear end portion of the jig 13. Interengagement of the cam 15 and the cam engaging piece 13c allows back-and-forth motion of the jig 13 by manipulation of the operating lever 14.

[0059] Turning next to Fig. 4, the initial treatment rotating cutter 3 and the secondary treatment rotating cutter 7 will be described in detail.

[0060] Fig. 4(A) is a partially sectioned side elevational view illustrating the initial treatment rotating cutter and the secondary treatment rotating cutter in association with the jig before they are coupled, and Fig. 4(B) is a partially sectioned side elevational view showing the state of coupling of the both cutters depicted in Fig. 4(A).

[0061] The initial treatment rotating cutter 3 has a cutting surface portion (a barrel-shaped cutting surface) 3a. The cutting surface portion 3a is of a tapered barrel-like configuration whose diameter is minimum at the distal end in the direction of insertion into a patient's body and maximum at the proximal end. The cutting surface portion 3a is stepped at the proximal end to provide an intermediate shoulder 3b extending integrally therefrom. The intermediate shoulder 3b is for engagement with the secondary treatment rotating cutter, and has a diameter smaller than the maximum diameter of the cutting surface portion 3a. The intermediate shoulder 3b is stepped at its rear end to provide a small-diameter shoulder 3c extending integrally therefrom. The small-diameter shoulder 3c has fitted thereon the tip end portion of the drive shaft 4. In the outer peripheral surface of the intermediate shoulder 3b there is formed a shallow annular groove 3e for locking the secondary treatment rotating cutter 7. The initial treatment rotating cutter 3

has a central hole 3d extending therethrough along the central axis for insertion of the guide wire 1.

[0062] The secondary treatment rotating cutter 7 is substantially annular in section. The rotating cutter 7 has a curved cutting surface portion 7a of a diameter larger than the maximum diameter of the initial treatment rotating cutter 3. Incidentally, the outside diameter of the distal end of the secondary treatment rotating cutter 7 is set nearly equal to the maximum diameter of the proximal end of the initial treatment rotating cutter 3 to provide a tight fit between the cutting surface portions 3a and 7a when the both cutters 3 and 7 are joined together. The secondary treatment rotating cutter 7 has an annular locking pawl 7b extending integrally from its inner periphery. The locking pawl 7b locks in the annular groove 3e of the initial treatment rotating cutter 3. The locking pawl 7b is tapered to be large in diameter at its extremity--this facilitates fitting the secondary treatment cutter onto the intermediate shoulder 3b of the initial treatment cutter.

[0063] Next, a description will be given of an operation for removing deposits from the narrowed vascular portion 2 by use of the medical instrument of the first embodiment.

[0064] The initial treatment begins with inserting the guide wire 1 into a blood vessel until the distal end of the guide wire 1 passes through the narrowed vascular portion 2. This is followed by navigating the initial treatment rotating cutter 3 over the guide wire 1 to the narrowed vascular portion 2 while rotating the cutter at low speed. At the instant the rotating cutter 3 reaches the narrowed vascular portion 2, the cutter 3 is rotated at high speed. And deposits in the narrowed vascular portion 2 are removed by the cutting surface portion 3a of the rotating cutter 3 for initial treatment.

[0065] In the case of performing treatment for further distending the narrowed vessel 2 in succession to the initial treatment, the rotating cutter 3 is once drawn out over the guide wire 1 from a patient's body together with the drive shaft 4 and the sheath 5 while at the same time leaving the wire 1 within the body (in the blood vessel). Without being taken off the guide wire 1, the rotating cutter 3 thus pulled out of the patient's body is fitted into and held in the cutter receiving concavity 13d of the jig 13 as shown in Fig. 4(A).

[0066] In this instance, the secondary treatment rotating cutter 7 is fitted and held in the base concavity 12 of the housing 11 of the controller 10 in advance. Operating the jig operating lever 14 to retract the jig 13 toward the housing 11 from the position shown in Fig. 4(A), the intermediate shoulder 3b of the initial rotating cutter 3 is pressed into the secondary treatment rotating cutter 7 as depicted in Fig. 4(B). At the instant the rear end shoulder of the cutting surface portion 3a of the initial treatment rotating cutter 3 abuts against the front end of the secondary treatment rotating cutter 7, the locking pawl 7b of the secondary treatment rotating cutter 7 locks in the annular groove 3e of the initial treatment rotating cutter 3. Thus the both cutters 3 and 7 are joined together to enlarge the diameter of the initial treatment rotating cutter 3 by the secondary treatment rotating cutter 7.

[0067] Following such interengagement of the both cutters 3 and 7, the jig 13 is opened to disengage the interengaged cutters 3 and 7 (a unit cutter) from the base concavity 12 and the cutter receiving concavity 13d, and the unit cutter is shifted over the guide wire 1 further toward the patient than the front-end tab 13a of the jig 13. Then the unit cutter is kept rotating at low speed and is inserted into the patient's body and down to the initially treated narrowed vascular portion 2 along the guide wire 1 remaining within the vessel. And the unit cutter is rotated at high speed to remove the remaining deposits on the vascular wall by the cutting surface portion 7a of the secondary treatment rotating cutter 7.

[0068] According to the first embodiment described above, in the case of performing again the treatment for distending the narrowed vascular portion 2 after the initial treatment, there is no need for replacing the rotating cutter 3 with a new one after completely pulling out all of the controller 10, the rotating cutter 3, the drive shaft 4 and the fixed sheath 5 from the patient's body as is required in the prior art. The medical instrument of the first embodiment allows ease in enlarging the diameter of the cutting surface portion simply by fitting the secondary treatment rotating cutter 7 on the rotating cutter 3 on the guide wire 1 extending out of the patient's body. Accordingly, a step-by-step treatment for removal of deposits from a narrowed vascular portion can be performed promptly and efficiently.

[0069] EMBODIMENT 2

[0070] Fig. 5 illustrates, in a partially sectioned side elevation, a jig for enlarging the diameter of

the rotating cutter of a medical instrument according to a second embodiment of the present invention.

[0071] A jig 16 shown in Fig. 5 has one-hand operated a lever mechanism. The jig 16 includes a pair of operating levers 16A and 16B pivotally interconnected by a pin P. The one operating lever 16A has at its upper extremity a cutter receiving seat 17 formed unitary therewith.

[0072] In the cutter receiving seat 17 there are formed an aperture 17a, a base concavity 17b for fitting and retaining therein the secondary rotating cutter 7, and a slit 17c for fitting therein the fixed sheath 5.

[0073] Through the aperture 17a of the cutter receiving seat 17 there is slidably inserted a press member 18. The press member 18 is substantially L-shaped in cross section, and has an engaging piece 18a for engagement with the upper extremity of the other operating lever 16B. The press member 18 has made therein a cutter receiving concavity 18b for receiving the initial treatment rotating cutter 3 and a slit 18c for receiving the guide wire 1.

[0074] In the case of using the jig according to the second embodiment, as shown in Fig. 5(A), the secondary treatment rotating cutter 7 is engaged and held in the base concavity 17b of the cutter receiving seat 17 in advance, whereas the initial treatment rotating cutter 3 is engaged in the cutter receiving concavity 18b of the press member 18 in advance, too. Squeezing the operating levers 16A and 16B, the intermediate shoulder 3b of the initial treatment rotating cutter 3 is pressed into the annular secondary treatment rotating cutter 7. By this, the both cutters 3 and 7 are combined into a unitary structure as shown in Fig. 5(B) to provide an enlarged-diameter cutting surface.

#### [0075] EMBODIMENT 3

[0076] Figs. 6(A) through (D) are sectional views illustrating, in association with a jig, rotating cutters of a medical instrument according to a third embodiment of the present invention.

[0077] Incidentally, Fig. 6 is also explanatory of the rotating cutter diameter enlargement procedure. In Fig. 6 the parts identical or corresponding to those in Figs. 1 to 4 are identified by the same reference numerals and no description will be repeated therefor.

[0078] In the first embodiment of Fig. 4 the initial treatment rotating cutter 3 and the secondary treatment rotating cutter 7 are joined together by interengagement of the annular groove 3e and the engaging pawl 7b.

[0079] On the other hand, in the third embodiment the cutting surface portion 3a and the intermediate shoulder 3b of the initial treatment rotating cutter 3 are reversely tapered to provide a stepped portion between them, and a front-half large-diameter concavity 7c and a rear-half small-diameter concavity 7d of the secondary treatment rotating cutter 7 are formed coaxially. A jig 21 is used to engage and press the secondary treatment rotating cutter 3 on and against the initial treatment rotating cutter 7. The jig 21 is provided with a jig seat 22 that pairs therewith.

[0080] The jig 21 and the jig seat 22 will hereinbelow be described in detail.

[0081] The jig seat 22 has a cutter receiving recess 22a. The cutter receiving recess 22a is a curved concavity, into which is fitted the rear half portion of the cutting surface portion 7a of the secondary treatment rotating cutter 7 from an intermediate section to the rear end in its axial direction.

[0082] The jig 21 has a cutter engaging concavity 21a (see Fig. 6(C)). The cutter engaging concavity 21a is for receiving the front half of the cutting surface portion 7a of the secondary treatment rotating cutter 7 from the intermediate section to the front end in its axial direction such that the front half of the cutting surface portion 7a undergoes plastic deformation in a direction in which it is pressed against the cutting surface portion 3a of the initial rotting cutter 3. Further, the jig 21 has a slit 21b. Through the slit 21b the guide wire 1 can be passed from the outside of the jig 21 to the cutter engaging concavity 21a inside thereof. Incidentally, the cutter engaging concavity 21a has a curved surface configuration substantially symmetrical to the recess 22a.

[0083] Next, a description will be given of the operation of the medical instrument according to the third embodiment.

[0084] For initial treatment of the narrowed vascular portion 2 shown in Fig. 1, the secondary treatment rotating cutter 7 is engaged and held in the recess 22a of the jig seat 22 in advance as depicted in Fig. 6(A). And initial treatment of the narrowed vascular portion 2 is performed by

the initial treatment rotating cutter 3 in the same manner as in the aforementioned first embodiment.

[0085] In the case of performing treatment for further distending the narrowed vascular portion 2 after the initial treatment, the rotating cutter 3 is once pulled out of the patient's body along the guide wire 1 held remaining in the body (in the blood vessel). And, as shown in Fig. 6(B), the rotating cutter 3 thus drawn out of the patient's body is fitted into the secondary treatment rotating cutter 7 on the guide wire 1. In this state, there is play between the cutting surface portion 3a of the initial treatment rotating cutter 3 and the secondary treatment rotating cutter 7.

[0086] To remove the play, as depicted in Fig. 6(C), the jig 21 is put on the guide wire 1 extending forwardly from the initial treatment rotating cutter 3 and is pushed to shift along the guide wire 1 in a direction of its engagement with the jig seat 22. Then, that portion of the secondary treatment rotating cutter which extends forwardly from the jig seat 22 is caused to undergo plastic deformation in conformity to the curved surface of the cutter engaging concavity 21a of the jig 21. Thus the extending portion of the secondary treatment rotating cutter 7 is pressed onto and hence firmly coupled to the cutting surface portion 3a of the initial treatment rotating cutter 3.

[0087] In this way, the both cutters 3 and 7 are interengaged into a one-piece structure such that the diameter of the initial treatment rotating cutter 3 is enlarged by the secondary treatment rotating cutter 7. And the thus interengaged cutters 3 and 7 (a unit cutter) are returned as a unit along the guide wire 1 to the initially treated narrowed vascular portion 2, after which the unit cutter is rotated at high speed to remove remaining deposits at the narrowed vascular site by the cutting surface portion 7a of the secondary treatment rotating cutter 7.

[0088] The jig 21 and the jig seat 22 in the third embodiment may also be installed in the controller 10 as is the case with the jig 13 shown in Figs. 1 to 4. Alternatively, they may also be formed as a squeeze-type operating handle structure and disposed on the fixed sheath 5 near the controller 10 as in the case of the jig 16 depicted in Fig. 5. To sum, the jig needs only to induce plastic deformation of the secondary treatment rotating cutter 7 so that it is pressed against and covers the outer peripheral surface of the initial treatment rotating cutter 3.

[0089] According to the third embodiment described above, too, it is possible to obtain the same working-effect as is obtainable with the afore-mentioned first embodiment.

[0090] EMBODIMENT 4

[0091] Fig. 7 is a perspective view illustrating an initial treatment rotating cutter and a secondary treatment rotating cutter according to a fourth embodiment of the present invention.

[0092] The initial treatment rotating cutter 3 in Fig. 7 has a plurality of grooves 23 cut in its outer peripheral surface. The rotating cutter 3 has cutting edges 24 formed by the grooves 23. These cutting edges 24 (a cutting edge group) form the cutting surface portion 3a of the initial treatment rotating cutter 3.

[0093] In the outer peripheral surface of the secondary treatment rotating cutter 7 there are cut a plurality of grooves 25. The grooves 25 form a plurality of cutting edges 26. These cutting edges 26 (a cutting edge group) form the cutting surface portion 7a of the secondary treatment rotating cutter 7.

[0094] That is, in the fourth embodiment the grooves 23 and 25 are cut as by laser beam machining in the outer peripheral surfaces of the initial treatment rotating cutter 3 and the secondary treatment rotating cutter 7, and opening edges of the grooves 23 and 25 are used as the cutting edges 24 and 26. These cutting edges 24 and 26 may also be in sharp pointed form integrally jutting up from the outer peripheral surfaces of the cutters 3 and 7.

[0095] According to the fourth embodiment, unlike in the case of a conventional cutting bar of the type that the mother-material metal surface of a rotating grindstone structure is coated with diamond grains by chromium plating or electrodeposition, the medical instrument is free from the possibility of the diamond grains dropping out through reaction forces from calcified, hard deposits on the narrowed vascular portion 2.

[0096] EMBODIMENT 5

[0097] Fig. 8 is a sectioned side elevational view illustrating the construction of a controller of a medical instrument according to a fifth embodiment of the present invention.

[0098] Fig. 9 is an enlarged sectioned side elevational view illustrating the construction of the controller of the medial instrument shown in Fig. 8.

[0099] Fig. 10 is a sectioned side elevational view showing the controller of the Fig. 8 medical instrument, with a sheath connector taken away.

[00100] As depicted in Fig. 8, the controller 10 has a housing 11. The housing 11 has a grip 11A integrally extending therefrom upwardly. The grip 11A has attached thereto a grip lever 30. The grip lever 30 has built therein a lever core bar 31, and the lever core bar 31 is pivotally mounted by a pin P1 on the grip 11A.

[00101] A lock lever 32 is connected to the pin P1. To a lower end portion 31a of the lever core bar 31 in the housing 11 is attached a motor holder 33 below the pin P1. In a mounting piece for mounting the motor holder 33 on the lever core bar 31 there is formed a guide slit 34. A guide pin 35 extending from the lower end portion of the lever core bar 31 is slidably received in the guide slit 34. The motor holder 33 holds therein a motor 36. On the output shaft of the motor 36 is fitted an eccentric cam 37. In the periphery of the eccentric cam 37 is fitted a bearing holder 39 through bearings 38. The bearing holder 39 has a depending pin 39a integrally extending from the underside of the holder centrally thereof.

[00102] In the housing 11 there is placed a cylindrical slider 40. The slider 40 is connected to the depending pin 39a so that it can reciprocate axially of the drive shaft 4. The slider 40 is biased by a spring 41 in a direction of retraction (a direction in which to pull out the drive shaft 4 from the patient's body). In the inner periphery of the slider 40 there is disposed an armature core 42. Inside the armature core 42 is disposed a rotor magnet 44 through an armature coil 43. The slider 40 has built therein a Hall sensor 45. The slider 40, the armature core 42, the armature coil 43, the rotor magnet 44 and the Hall sensor 45 constitute a drive shaft rotating brushless motor assembly 46 in the housing 11.

[00103] Inside the rotor magnet 44 there is rotatably disposed a sleeve-like hollow rotary shaft 47. A sleeve-like chuck member 48 is axially movably inserted in the hollow rotary shaft 47. The chuck member 48 has at one end (front end) in its axial direction a chuck pawl 48a integrally formed therewith for chucking the drive shaft 4. On engaging with one end of the

hollow rotary shaft 47 in its axial direction, the chuck pawl 48a contracts diametrically to chuck the drive shaft 4. Shifting in a direction to disengage from the one end of the hollow rotary shaft 47, the chuck pawl releases the drive shaft 4. To the other end of the chuck member 48 in its axial direction is threadably attached a chuck connecting member 49. The chuck member 48 and the chuck connecting member 49 are biased by a spring 50 in a direction in which the chuck pawl 48a chucks the drive shaft 4. With such an arrangement, the hollow rotary shaft 47, the chuck member 48, the chuck pawl connecting member 49 and the spring 50 constitute a drive shaft 4 chucking mechanism. Incidentally, the chuck member 48 and the chuck connecting member 49 need only to be configured as a single sleeve that has the chuck pawl 48a formed integrally therewith at one end in the axial direction and allows the insertion therethrough of the drive shaft 4.

[00104] In the rear of the chuck pawl connecting member 49 is situated a cylinder knob 51 for chucking release use. The cylinder knob 51 is held by a cylinder holder 52 in the housing 11 so that it is axially shiftable to abut against the rear end of the chuck pawl connecting member 49. The cylinder knob 51 is biased by a spring 53 in a direction away from the chuck pawl connecting member 49.

[00105] To the front end of the housing 11 a sheath connector 54 is detachably secured about the drive shaft 4. The sheath connector 54 has fitted thereon the soft fixed sheath 5. The sheath connector 54 has pressed therein a mechanical seal 55, and the mechanical seal 55 makes sliding contact with the drive shaft 4. A physiological salt solution supply tube 56 communicates with the sheath connector 54.

[00106] Next, a description will be given of the operation of the controller 10.

[00107] After the rotating cutter 3 has been navigated over the guide wire 1 to the narrowed vascular portion 2 as shown in Fig. 1, the brushless motor 46 for driving the drive shaft is brought into operation. Then the drive shaft 4, the chuck pawl 48a chucking the drive shaft 4 and the chuck pawl connecting member 49 coupled to the rear end of the chuck member 48 rotate as a unit with the rotor magnet 44. By this, the rotating cutter 3 at the distal end of the drive shaft 4 rotates to remove deposits in the narrowed vascular portion 2.

[00108] Putting the motor 36 into operation during rotation of the rotating cutter 3, the eccentric cam 37 rotates and the bearing holder 39 also rotates eccentrically as a unit with the eccentric cam 37. Then the slider 40 connected to the depending pin 39a of the bearing holder 39 reciprocates axially thereof. As a result, the drive shaft 4 reciprocates axially thereof through the drive shaft driving motor assembly 46 provided unitary with the slider 40 and the chuck member 48. Accordingly, the rotating cutter 3 at the extreme end of the drive shaft 4 is imparted a rotary motion as well as a reciprocating motion along the guide wire 1--this ensures increasing or stabilizing the cutting force of the rotating cutter 3 for removing deposits in the narrowed vascular portion 2.

[00109] In the case of treating the narrowed vascular portion 2 for further distending the vessel after initial treatment of the narrowed vascular portion 2 by the rotating cutter 3, the rotating cutter 3 and the drive shaft 4 are once pulled out along the guide wire 1 from the patient's body. At this time, the drive shaft 4 is released from chucking by the chuck pawl 48a. In this case, pushing cylinder knob 51 for chucking release use against the spring 53, the chuck pawl connecting member 49 and chuck member 48 are pushed forward by the cylinder knob 51 against the spring 50, and the chuck pawl 48a moves forwardly of the front end of the hollow rotary shaft 47 and opens. Thus the drive shaft 4 is released from chucking by the chuck pawl 48a, and hence the drive shaft 4 can be easily pulled out along the guide wire 1 from the patient's body.

[00110] During removal of deposits in the narrowed vascular portion 2 by the rotating cutter 3 or by the secondary treatment rotating cutter 7 mounted on the rotating cutter 3 as a unitary structure therewith, a physiological salt solution is supplied from the tube 56 into the sheath connector 54. The physiological salt solution flows through the fixed sheath 5 and gushes out toward the rotating cutter 3.

[00111] According to this method, since the mechanical driving assembly for the controller 10 is formed by a combination of the motor 36 provided with the eccentric cam 37 for vibrating use and the brushless motor 46 for drive shaft rotating use, it is possible to impart combined cutting forces by rotary and reciprocating motions to the rotating cutter 3. This ensures increasing or stabilizing the cutting force of the rotating cutter 3 for removing deposits

from the narrowed vascular portion 2. Further, the rotating cutter 3 and the sheath 5 can be easily inserted into the guiding catheter 6 with less friction.

[00112] As is evident from the above description, according to the present invention, in the case of enlarging the diameter of the rotating cutter after initial treatment of the narrowed vascular portion, the rotating cutter is once pulled out, together with the drive shaft and the fixed sheath, from the patient's body along a guide wire left remaining in the patient's body, and the diameter of the rotating cutter thus drawn out of the body can be enlarged on the guide wire. Accordingly, in the case of distending the narrowed vascular portion by further cutting, there is no need for replacement of the rotating cutter after completely removing it and the controller from the guide wire. This permits quick distention of the narrowed vascular portion by removing deposits therefrom.